

K980913

JUL 1 1998

**510(k) Summary of Safety and Effectiveness**

Galil Medical - CRYO-HIT™ System  
510(k) Number K \_\_\_\_\_

*\* For Release Upon Request Only \**

**Company Name:**

**Galil Medical Ltd.**

**Contact Person:**

Shaik Shatzberger, President and CEO  
Elisabeth Sadka, Regulatory manager

Telephone: +972-4-959 10 80  
Fax: +972-4-959 10 77

**Trade Proprietary Name:**

**CRYO-HIT™.**

**Classification Name:**

**CRYOSURGICAL UNIT**

**Classification:**

**GEH**

**Predicate Devices:**

CRYOcare - ENDOcare.  
CMS AccuProbe System.

297

**Indication for Use:**

CRYO-HIT™ is intended for cryogenic destruction of tissue during surgical procedures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurosurgery, thoracic surgery, ENT, gynecology, oncology, proctology, and urology for the ablation of tissue, including liver metastases, skin lesions, warts, and prostate tissue.

**Device Description:**

CRYO-HIT™ is a cryosurgical system that consists of:

1. a structural enclosure (The CRYO-HIT™ system is housed in a rack assembly mounted on four cater wheels for ease of transport),
2. a power control panel,
3. a computer and control assembly,
4. a gas supply system: Argon (cooling) and Helium (thawing) gas reservoirs,
5. a gas distribution system (valve assembly ),
6. Accessories: cryoprobes (named *galil-ee probes*), temperature sensors and a remote control unit.

The different CRYO-HIT™ models have the same performance, technology and intended use. The only difference between them are the number of probe ports available in each model (3-probe, 5-probe, 7-probes and 8-probe configurations) and the number of temperature sensor ports ( to meet the needs of different customers).

The probes used for the 3-probe, 5-probe, 7-probes and 8-probe configurations are exactly the same.

**Technological Characteristics and Substantial Equivalence:**

The CRYO-HIT™ System has the same intended use, and very similar principle of operation and technological characteristic as ENDOcare and CMS Accuprobe System, thus the CRYO-HIT™ System is substantial equivalent to these legally marketed predicate devices.

298



JUL 1 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Galil Medical Limited  
c/o Mr. Jonathan S. Kahan  
Hogan & Hartson  
555 Thirteen Street, N.W.  
Washington, DC 20004

Re: K980913  
Trade Name: Cryo-Hit Models EP3T3, EP5T2, EP5T5, EP7T5, EP8T5  
Regulatory Class: II  
Product Code: GEI  
Dated: June 11, 1998  
Received: June 11, 1998

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

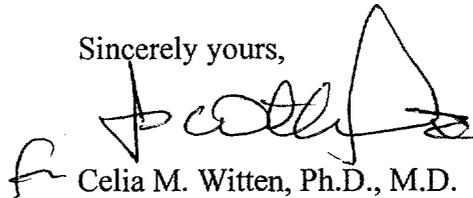
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

Page 2 - Mr. Jonathan Kahan

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over a large, stylized, handwritten letter 'f'.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

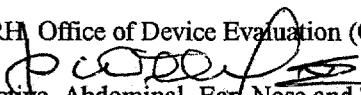
**510(k) Number (if known):** \_\_\_\_\_

**Device Name:** CRYO-HIT™ System

**Indications for Use:**

CRYO-HIT™ is intended for cryogenic destruction of tissue during surgical procedures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurosurgery, thoracic surgery, ENT, gynecology, oncology, proctology, and urology for the ablation of tissue, including liver metastases, skin lesions, warts, and prostate tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRA Office of Device Evaluation (ODE)  
(Division Sign-off)   
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices

510(k) Number K980913

Prescription Use    
(Per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_